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DOI: <https://doi.org/10.1097/MAO.0000000000000791>

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ZORA URL: <https://doi.org/10.5167/uzh-112798>

Journal Article

Published Version

Originally published at:

Laske, Roman D; Rösli, Christof; Pfiffner, Flurin; Veraguth, Dorothe; Huber, Alex M (2015). Functional Results and Subjective Benefit of a Transcutaneous Bone Conduction Device in Patients With Single-Sided Deafness. *Otology Neurotology*, 36(7):1151-1156.

DOI: <https://doi.org/10.1097/MAO.0000000000000791>

Functional Results and Subjective Benefit of a Transcutaneous Bone Conduction Device in Patients With Single-Sided Deafness

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Objective: To analyze speech discrimination scores and subjective benefit of a transcutaneous bone conduction device (tBCD) in adults with single-sided deafness (SSD).

Study Design: Prospective cohort study.

Setting: Tertiary referral center.

Patients: Nine adults with SSD for more than 1 year and normal hearing on the contralateral side (PTA <30 dB HL) were implanted with a tBCD.

Interventions: Transmastoidal implantation of a Bonebridge (BB, MED-EL) tBCD.

Main Outcome Measures: Aided and unaided speech discrimination scores in three different spatial settings were measured using the Oldenburg sentence test (OLSA). Quality of life was assessed by two questionnaires, the Bern Benefit in Single Sided Deafness Questionnaire (BBSS) and the Speech, Spatial and Qualities of Hearing scale for benefit questionnaire (SSQ-B).

Results: Speech discrimination scores measured by OLSA showed a mean signal-to-noise ratio improvement of 1.7 dB

SPL for the aided condition compared with the unaided condition in the setting where the sound signal is presented on the side of the implanted ear and the noise is coming from the front ($p < 0.05$). In the other two settings (signal and noise from front; signal from normal hearing ear and noise from front), the signal-to-noise ratio did not change significantly. This benefit became manifest after 6 months. Good satisfaction was indicated by positive results on the questionnaires.

Conclusion: Speech discrimination in noise for patients implanted with the BB is comparable with patients with other bone conduction hearing aids. A learning curve is clearly detectable. The subjective benefit was rated positively by the patients. With the advantage of intact skin conditions after implantation, the BB is an adequate option for patients with SSD.

Key Words: Single-sided deafness—Bone conduction—Bone conduction hearing aid—Speech—Discrimination.

Otol Neurotol 36:1151–1156, 2015.

Single-sided sensorineural hearing loss or single-sided deafness (SSD) results in a decline in speech recognition in noise because of the head shadow effect (1,2), and a decrease in sound localization. Most patients affected by SSD report a hearing handicap (3). Although some patients cope well with SSD and prefer no treatment, others are highly disturbed and want treatment.

There is a growing number of different auditory rehabilitation options available today (4): 1) Contralateral routing of signal (CROS) hearing aid systems are a noninvasive option, where sound is transmitted from the deaf ear to the better ear by wireless technology. The

main drawback is that the better ear must also be fit with a device in addition to the deaf ear, where the microphone is located (5,6); 2) Bone-anchored hearing aid systems transmit sound to the better side by bone conduction (BC). This technique was introduced in 1977 (7) and was originally used for conductive and mixed hearing losses before the indication was expanded for use with SSD, and Food and Drug Administration approval was acquired in 2002 (8). Several studies have shown significant speech understanding improvement and improvement of quality of life for SSD (9–13); 3) Nonsurgical removable BC prosthetic hearing devices transmit sound via the teeth (14); 4) The cochlear implant is an invasive option with the goal of restoring true binaural hearing. This option is being offered to a growing number of patients with SSD (15,16).

The Bonebridge (BB, MED-EL) transcutaneous BC device (tBCD) was introduced in 2012 (17–19). The

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Conflicts of Interest and Source of Funding: None.

system consists of a BC implant with a floating mass transducer, an electrical demodulator, and a receiver coil that is fully implanted, leaving intact skin conditions after wound healing. The sound processor including microphones and battery is worn externally. In an experimental cadaver study (17), noninferiority of the BB in comparison with a percutaneous BC device (pBCD), the BAHA (Cochlear Bone Anchored Solutions AG, Mölnlycke, Sweden), was shown for both, the stimulation of the same-sided cochlea as well as the opposite cochlea for promontory vibration. Clinically, tBCDs have been used primarily for resolution of conductive and mixed hearing loss (20).

To our knowledge, no reports on tBCD for use with SSD patients have been published. The aim of this study was to analyze functional and subjective benefit after implantation of a tBCD in patients with SSD.

PATIENTS AND METHODS

Subjects

This study was designed as a prospective cohort study including nine adult patients with SSD undergoing implantation of a tBCD (BB, MED-EL) between October 2012 and September 2013. All implantations were performed in one tertiary referral center. The study protocol was approved by the local ethic committee (Study Code 2012BB003, Ref. KEK-ZH-Nr:2012-0240), and the study was carried out according to the declaration of Helsinki (21).

Audiologic SSD inclusion criteria were defined as nonmeasurable BC thresholds for the frequencies of 500, 1,000, 2,000, and 3,000 Hz or as a maximal speech discrimination score of 50% at a presentation level of 100 dB SPL, or less on the side of the affected ear, measured with appropriate masking in the contralateral ear and under headphones. In addition, the air conduction (AC) pure tone average (PTA, 500, 1,000, 2,000, and 3,000 Hz) had to be 30 dB HL or less on the unaffected side.

Patients fulfilling these inclusion criteria were counseled about four rehabilitation options: 1) no intervention, 2) use of a CROS hearing aid, 3) pBCD implantation, and 4) BB implantation. All included subjects tested a CROS hearing aid and a BC device mounted on a headband for several weeks in everyday situations prior to their final decision. Patients were not counseled about a cochlear implant because this option for SSD is not covered by medical insurance in the country where the study was conducted.

The tBCD was implanted as described by Manrique et al. (22) under general anesthesia. An L-shaped retroauricular skin incision was used, and a counter-rotating muscle-periost flap was elevated. The skin thickness was measured and subcutaneous tissue was removed if necessary. Next, a notch of the size of the tBCD (16 mm diameter, 9 mm depth) was drilled into the mastoid, and the device was fixed with two screws. The muscle-periost flap was adapted and the skin closed allowing a two-layer closure of the flap.

The first fitting took place approximately 4 to 5 weeks after implantation. Target curves were calculated from the BC of the unaffected ear using the SYMFIT 6.1 (MED-EL, Austria) and Connexx V6.5 (Siemens, Germany) software. The second fitting appointment was scheduled 6 months later, and patients were instructed to call for an earlier appointment if necessary.

Audiometry

Pre- and postoperative pure tone audiometry for each side at 500, 1,000, 2,000, 3,000, and 4,000 Hz was conducted in accordance with ISO 8253-1 and 8253-3. Frequencies with no responses

at the maximum level of the audiometer were entered as maximum output plus 5 dB. Preoperative maximal speech understanding was determined using the Swiss version of the German Freiburger test (monosyllables) (23). Speech perception in noise was measured using a closed-set sentence test, the Oldenburg Sentence Test (OLSA) (24). The OLSA-noise (pseudo continuous) served as the noise source and was located in the frontal position (N_0) in all spatial settings. One long sentence list was used to measure each situation. The sound signal was presented from three different positions resulting in three test setups (S_0N_0 , $S_{CL}N_0$, $S_{BB}N_0$), as shown in Figure 2b. The noise level was set at 65 dB SPL, and the speech level changed adaptively according to the number of words repeated correctly (25). Results were measured as a signal-to-noise ratio (SNR) in dB, indicating the difference of the sound signal level at which 50% of the words were repeated correctly with a constant noise level of 65 dB SPL. The SNRs for stimuli delivered via each of the three different setups were measured once with the implant turned on as the aided condition and once with the implant turned off as the unaided condition. Thus, "benefit" was defined as a nominal decrease of the SNR, expressed as a negative value, calculated as the difference of the SNR between the aided and unaided condition. Patients used the universal setting of the device, where the microphone is set in omnidirectional mode. They were asked to keep their head stable and to remain looking at the speaker in the frontal position. All nine patients were tested approximately 12 months after implantation (mean, 13 ± 2.5 months; range, 10.5–19.5 months). Six of the nine patients were also tested at the fitting appointment approximately 30 days after implantation (mean, 28.5 ± 7.7 days, range 20 to 39 days) and at an intermediate interval of at least 6 months after implantation (mean, 7 ± 0.5 months; range, 6.5–8 months).

Questionnaires

Two questionnaires were administered for each patient: 1) A modified version of the Speech, Spatial and Qualities of Hearing questionnaire (SSQ) (26), the SSQ-B (27); 2) the Bern Benefit in Single-Sided Deafness Questionnaire (BBSS) questionnaire (28). Both questionnaires specifically ask participants to compare their hearing abilities in the aided condition versus the unaided condition on an ordinal scale ranging from -5 (much worse) to $+5$ (much better). The SSQ-B is divided into three categories and consists of 49 questions; the BBSS consists of 10 questions.

RESULTS

Demographics

A total of nine patients (four female, five male) with SSD matched the inclusion criteria. Table 1 provides demographic, etiologic, and preoperative speech discrimination score data. The mean (\pm SD) age at implantation was 52 (± 15) years. The implantation was performed on the left side in three, and on the right side in six patients. The most common cause for SSD was acute sensorineural hearing loss (SNHL) (three of nine), followed by labyrinthitis (two of nine). One patient was previously implanted with a pBCD system 6.5 years earlier. The decision to change to a tBCD was made due to recurring local infections and skin overgrowth. For eight patients, the tBCD implantation was the first surgical intervention for SSD.

The mean follow-up period was 16 months (range, 11–22 months). Placement of the implant into the mastoid was possible in all patients without the need for

TABLE 1. Demographic and clinical data

Patient	Age at Surgery	Sex	Pathology	Side of SSD	Maximal Speech Discrimination Score of Implanted Ear
1	57 yr	M	Acute SNHL	Left	0%
2	57 yr	F	Acute SNHL	Right	0%
3	49 yr	F	M. Meniere	Right	40%
4	46 yr	M	Labyrinthitis	Right	0%
5	18 yr	F	Progressive SNHL	Left	0%
6	42 yr	M	Acute SNHL	Right	0%
7	62 yr	F	Temporal bone fracture	Right	10%
8	65 yr	M	Viral infection in childhood	Left	5%
9	69 yr	M	Labyrinthitis	Right	0%

M, male; F, female.

retrosigmoidal placement. In one patient, the tBCD was in contact with the dura of the middle cranial fossa and the sigmoid sinus; however, there was no relevant impression made on these structures. In one patient, prolonged swelling in the wound region occurred, which resolved without further intervention. In a second patient, oral antibiotic therapy was necessary because of a postoperative wound infection, which resolved completely after 1 week of treatment. No patient had to undergo revision surgery.

Audiometry

Preoperatively, seven patients had no measurable BC thresholds on the affected ear side. Two patients had measurable BC thresholds resulting in BC PTAs on the affected side of 51 dB HL and 64 dB HL, respectively; however, these patients had speech discrimination scores of 40% and 0% at 100 dB SPL, respectively. The better ear had an AC PTA of 20 dB HL or better in 7 patients, and in 2 patients, the AC PTA was between 20 and 30 dB HL (Fig. 1). The pre- and postoperative AC and BC PTAs did not change significantly for either ear.

The OLSA results for all patients ($n = 9$) in aided and unaided conditions 12 months after the operation are summarized in Figure 2a. The corresponding test setups

are shown below in Figure 2b. For test situation 1 (S_0N_0), the mean SNR in the unaided condition was -2.82 dB and -2.14 dB in the aided condition. In situation 2 ($S_{CL}N_0$), the mean SNR increased from -7.27 to -6.52 dB. In situation 3 ($S_{BB}N_0$), the SNR decreased from -1.73 to -3.38 dB. The change was statistically significant only for situation 3 ($p < 0.05$, repeated ANOVA with Bonferroni correction).

The OLSA was measured at three time points postoperatively (1, 6, and 12 months) in 6 patients (3 of the 9 patients were measured only at 12 months, postoperatively). The difference of the SNR between the aided and unaided conditions at the different time points is shown in Figure 3 and represents functional benefit. One month after the operation, the benefit was small (SNR difference of -0.9 dB) and not statistically significant. After 6 months, the benefit increased and became significant ($p < 0.05$, repeated ANOVA with Bonferroni correction) when the SNR difference changed to -2.1 dB. After 12 months, the benefit in the OLSA increased slightly again as the SNR reached -2.2 dB and remained statistically significant ($p < 0.05$) compared with the unaided condition.

Questionnaire

Six patients completed the questionnaires at 6 months after tBCD implantation. The questionnaires of 3 patients were received later (12, 14, and 20 months after implantation). As shown in Figure 3, the benefit at 6 and 12 months is comparable. Therefore, the questionnaires were analyzed together.

Figure 4 illustrates the mean values for the 10 questions of the BBSS. The mean results for each question were positive, meaning that on average, the patients had good benefit from the device. However, the amount of benefit among subjects varied by up to 4.5 points. One patient reported no benefit and answered all questions as negative or 0, while all other patients responded only with positive values. The patient with the lowest score for the BBSS also showed the lowest score on the OLSA. A statistically significant association (Spearman rank correlation coefficient $R = 0.72$, $p = 0.03$) exists between subjective benefits (mean BBSS score) and objective

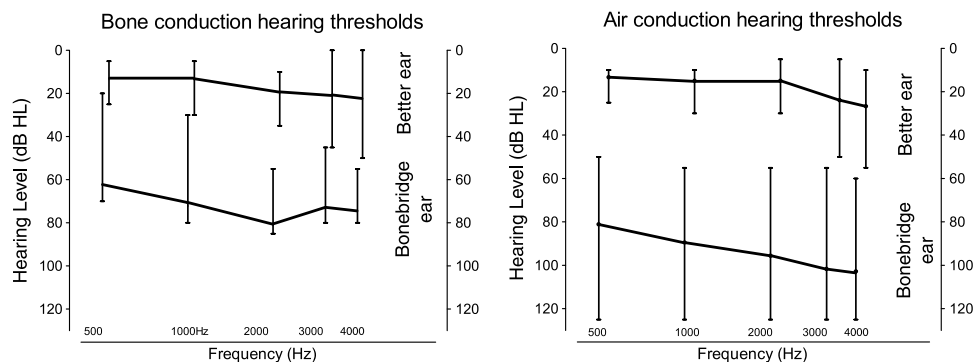


FIG. 1. Audiometric data. Air conduction and BC hearing thresholds of the better ear and the ear implanted with a tBCD (dB HL), shown as mean (graph) with range.

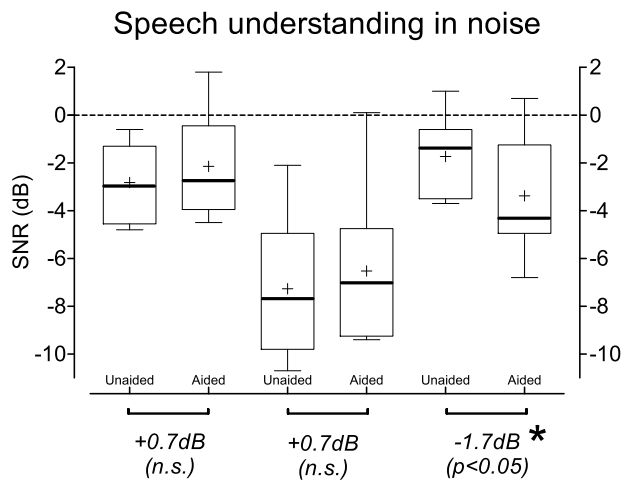


FIG. 2. Speech understanding in noise and test setups. a) SNR in the OLSA for the aided and unaided condition. In the upper part, results are shown as box-and-whisker diagrams with mean (+) and range. n.s., nonsignificant ($p > 0.05$), $n = 9$. b) on the left: test situation 1 (S_0N_0); in the middle: test situation 2 ($S_{CL}N_0$); on the right: test situation 3 ($S_{BB}N_0$). S, position of sound signal source (speech); N, position of noise source.

speech in noise score (mean of absolute SNR in all three aided conditions). As expected, localization of sound is the most difficult task for SSD subjects resulting in the lowest score for question 9 of the BBSS (“To localize a sound source, such as a honking car. For me, this is: ...”) with a mean score of 0.44.

Figure 5 illustrates the results from the SSQ-B. The mean score for all questions combined was positive. The speech section of the SSQ-B (Fig. 5a) yielded the most positive scores while results were somewhat closer to 0 for the spatial (Fig. 5b) and qualities sections (Fig. 5c). For the BBSS, most of the negative values from all sections originated from one patient, who correspondingly showed the lowest improvement on the OLSA in the

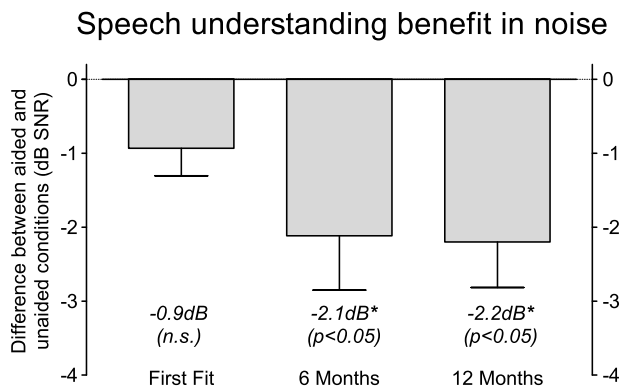


FIG. 3. Speech understanding benefit improvement over time. Difference of SNR in the OLSA for aided and unaided condition in test setup 3 is shown as bar (mean) with SEM. First fit was done 1 month postoperatively. Statistical analysis was done in comparison to 0 (no benefit).

aided condition. This patient is listed as Nr. 6 in Table 1. After 10 years of SSD due to acute sensorineural hearing loss, he sought auditory rehabilitation because of a new job in the noisy environment of a bar/restaurant. At the time of surgery, his better hearing ear showed a notched hearing loss with thresholds of 30 dB HL at 3,000 Hz, 35 dB HL at 4,000 Hz, and 45 dB HL at 6,000 Hz. The pre- and postoperative course was uneventful.

DISCUSSION

The primary goal of this study was to evaluate the clinical benefit of a tBCD for patients with SSD. We chose two different approaches to evaluate the patients' benefit, the OLSA to measure objective audiometric benefit and two questionnaires to evaluate subjective benefit.

The three different test setups for the OLSA represent three situations that are encountered in everyday life (Fig. 2b). Situation 1 simulates a conversation in noise. Situation 2 is designed to measure the negative effect a CROS system might cause by adding an additional noise signal, and situation 3 simulates the head shadow effect, a situation in which maximal improvement in speech recognition in the aided condition is expected. The measurements showed a small, but not significant, decrease of SNR between the aided and unaided conditions in situations 1 and 2 at 12 months after the surgery (Fig. 2a). Speech recognition scores showed that an amplified noise signal does not affect the speech signal in situations with noise coming from the frontal direction and the speech signal either from the unaffected side or from the front (Fig. 2b, situations 1 and 2). A significant improvement

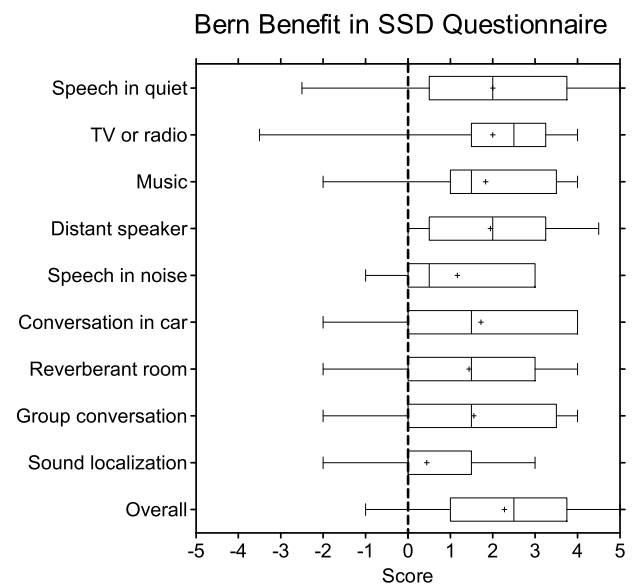


FIG. 4. BBSS results. y axis indicates the order of the questions; x axis, the scale that was used for the participant's response. Results are shown as boxplots with mean (+), median (horizontal line) and whiskers (range).

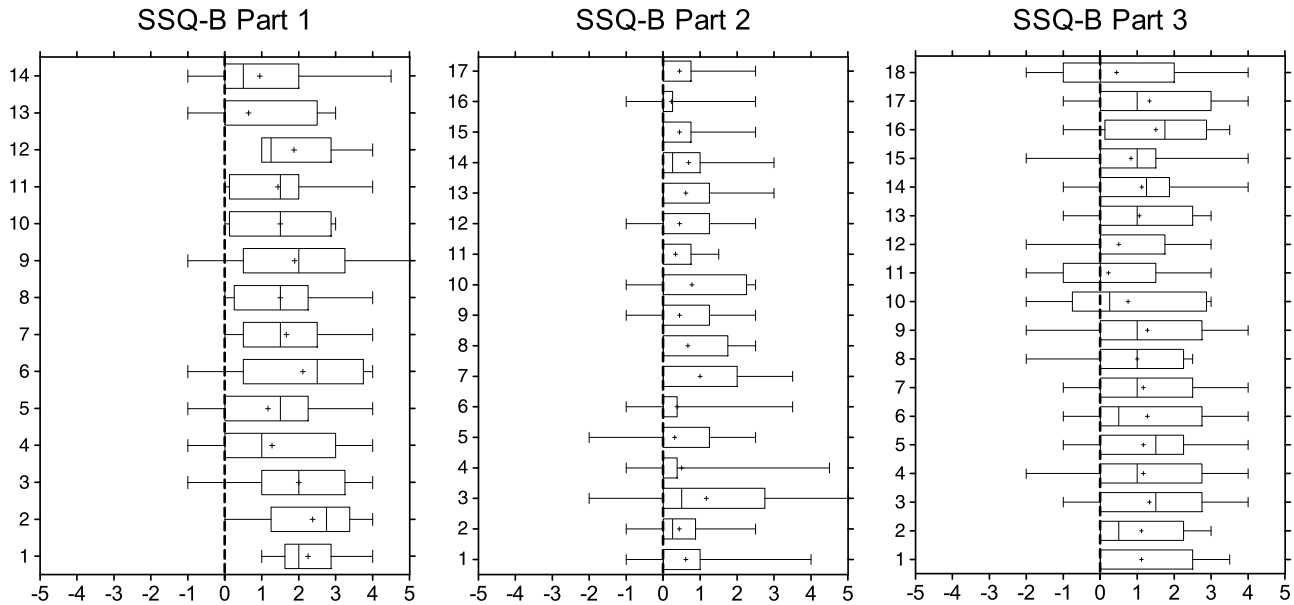


FIG. 5. SSQ-B results. Part 1, Speech; Part 2, Spatial; Part 3, Qualities. y axis indicates the order of the questions, x axis the scale that was used for the participant's response. Results are shown as boxplots with mean (+), median (horizontal line), and whiskers (range).

of -1.65 dB SNR was found for situation 3. This improvement is lower compared with findings with a BAHA system that reported improvements of -2.1 to -3.9 dB (29–31) (8). One reason for this difference may be the setting of the microphone (omnidirectional) compared with a directional microphone mode. However, it was shown in another study (32) that the setting of the microphone (omnidirectional vs directional) has no significant effect on speech understanding when measured in a setup such as in situation 3 ($S_{90}N_0$) in our study. One of our patients did not benefit from the device in any categories. Because of the small number of patients included, the effect of a nonresponder has a large impact on the overall results. However, this type of study is limited by the small number of patients meeting the inclusion criteria. It is difficult to judge the superiority of one system over another (i.e., tBCD vs pBCD), because no direct comparison of different devices in a randomized clinical trial is possible because of ethical considerations. An experimental comparison in cadaver heads of the BB and the BAHA did not show a significant difference between the devices with respect to vibration of the skull measured on the promontory (17). One of the patients included was previously implanted with a pBCD. Although he described inferior hearing quality with the tBCD in comparison with his previous device, he was very satisfied with the tBCD because of the lack of recurrent local infections.

An interesting finding was the improvement in situation 3 after an extended follow-up period (Fig. 3), indicated by a decrease in SNR. After 1 month, improvement was not significantly different from zero. Only after 6 months a significant decrease of SNR was observed, and after 12 months, SNR decreased further. This finding

stresses the importance of experience for patients with SSD provided with a tBCD and helps in counseling them preoperatively. It remains unclear whether a longer follow-up period would produce further change in SNR.

Our results only showed significant benefit in speech understanding for situation 3, whereas no improvement in SNR was found for situations 1 and 2. The question remains open as to whether the audiologic improvement in situation 3 results in better quality of life with regard to hearing. Therefore, patient satisfaction plays a crucial role in evaluating a new device for SSD treatment. The outcomes of the BBSS and the SSQ-B questionnaires used in this study were generally positive (89%). Only one patient (11 %) was dissatisfied, which corresponds to the findings of others (33).

The association between duration of deafness and growth of benefit expressed as the difference between benefit after first fit and after 12 months (Fig. 3) was statistically significant (Spearman rank correlation coefficient $R = -0.77$, $p < 0.01$). Overall, patients with longer lasting SSD needed more time to reach satisfactory speech recognition results than did those with a shorter duration. It remains unclear whether follow-up over a longer period of time would further increase SNR benefit differently depending on the duration of deafness prior to first fit.

The primary advantage of a tBCD as compared with a pBCD is the integrity of the skin. The risk of a recurrent infection is much smaller, and the microphone is clearly separated from the sound generator, resulting in less acoustic feedback (17). When the outer processor is not worn, the flatness of the implant and the intact skin conditions might look more natural, adding to a possible positive psychological aspect. In addition, the device might pose less of an obstacle in comparison with a metal screw when wearing head protection such as helmets. The

BBSS and SSQ-B did not have specific questions concerning these differences, and we cannot draw any final conclusion about these factors affecting quality of life.

The patients did not experience any postoperative complications that affected the outcome of the operation. Most patients had both subjective and objective benefit from the device.

CONCLUSION

Speech discrimination in noise for patients with a BB is comparable to patients with other BC hearing aids. A learning curve of up to 6 months was observed. The subjective benefit was rated positively by the patients. With the advantage of intact skin conditions after implantation, we consider the BB to be an adequate option for patients with SSD.

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